Translating the Research Diagnostic Criteria for Temporomandibular Disorders into Malay: Evaluation of Content and Process

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Aims: To develop a Malay-language version of the Axis II Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) through a formal translation/back-translation process and to summarize available data about the psychometric properties of the translated scales. ***Methods:*** *To cross-culturally adapt the instrument, the RDC/TMD underwent translation using a forward-backward method. Subjects were recruited to test the congruency between translated and original versions of the RDC/TMD. The psychometric properties of 3 domains (Graded Chronic Pain Scale, Nonspecific Physical Symptoms, and Depression) of the RDC/TMD were examined, and the literature on this topic was reviewed.* ***Results:*** *All the items scored 93% to 100% congruency. Cronbach's alphas for Graded Chronic Pain Scale, Nonspecific Physical Symptoms, and Depression were 0.77, 0.71, and 0.88, respectively (n = 40). The test-retest reliability of scores (intraclass correlation coefficient [ICC]) and levels (Spearman's rho) for these domains showed ICCs of 0.97, 0.94, and 0.95, respectively, with a lowest ICC value of 0.84 (n = 40); the Spearman's rho values were 0.93, 0.74, and 0.74, respectively. The discriminant validity between patients with pain symptoms (n = 40) and normal pain-free controls (n = 40) were statistically significant (*P < .001*). These correlations provide support for the internal consistency and validity of the Graded Chronic Pain Scale, Nonspecific Physical Symptoms, and Depression domains of the translated version of the RDC/TMD, which were found to be comparable to the psychometric properties of the original and other international translated versions.* ***Conclusion:*** *The cross-cultural adaptation of the RDC/TMD into the Malay language is suitable for use in Malaysia.* J OROFAC PAIN 2008;22:131–138

Key words: cross-cultural adaptation, internal consistency, temporomandibular disorders, translation, validity

The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) provide a systematic method for examining, diagnosing, and classifying the major subtypes of temporomandibular disorders (TMD). Since their introduction in 1992,[1] the RDC/TMD have been used internationally as an instrument in epidemiologic surveys, in clinical research settings in the management of orofacial pain, and in clinical trials.[2–5]

The RDC/TMD is a standardized and systematic set of clearly defined operational clinical measurement methods which has demonstrable reliability, validity, and clinical utility.[6] The major strength of the RDC/TMD lies in its dual-axis system, which helps

define the relationship between the various elements that constitute pain. Axis I of the RDC/TMD records the examiner's clinical physical findings and assigns a diagnosis or a combination of diagnoses, the 3 major groups being muscle disorders, disc displacements, and other joint conditions (arthralgia, osteoarthritis, and osteoarthrosis). The Axis II profile consists of several components derived from self-reported ratings on Likert scales and endorsement of symptoms or limitations on categorical scales. The profile measures perceived pain intensity, pain-related disability, resulting limitations, depression, and nonspecific physical symptoms suggesting somatization tendencies.

The RDC/TMD is a dual-axis questionnaire. Axis II of the RDC/TMD consists of 87 items, all made up of nominal responses and categorical responses. In many cases responses are made on a Likert scale ranging from 0 (none) to either 4 or 10 (extreme), depending on the respective item. The SCL-90 is a checklist of symptoms; the patient indicates the extent to which he or she has been bothered by specific symptoms in the past month on a 0 to 4 scale. In Axis II of the RDC/TMD, depression is judged on the basis of 20 items derived from the SCL-90, while nonspecific physical symptoms are judged on the basis of 12 items from the SCL-90, all rated on a Likert scale from 0 to 4. Normative data defining cutoff scores for normal, moderate, and severe levels of depression and nonspecific physical symptoms were provided by a large population-based study.[1]

The RDC/TMD has been used in numerous clinical research studies to characterize physical, psychologic, and psychosocial factors associated with TMD as well as with the relationship among these factors.[3,5,7–10] To date, up to 20 translated versions of the RDC/TMD either in part or in whole have been produced. These are referred to in the RDC/TMD Consortium website (http://rdc-tmdinternational.org/translations/Prog050217.pdf). Most of the translations were created through the process of forward and back-translation of the original RDC/TMD. Cultural equivalency has only been established in the Dutch and Portuguese versions.

In Malaysia the population consists of 3 main ethnic groups: Malays, Chinese, and Indians. These groups are proficient in either their own mother tongue, English, or both. The Malay language or the Bahasa Malaysia is the official language of Malaysia.

Cultural and sociodemographic differences limit the usefulness of the original version of RDC/TMD around the world. To assess TMD in the local population for multicenter comparison, there is therefore a need to translate the original RDC/TMD into the Malay language, a language understood by most in Malaysia. The present study was carried out with the aim of translating the RDC/TMD into the Malay language and assessing its reliability and validity in the Malaysian population.

Materials and Methods

Translation Process

Guidelines for cross-cultural adaptation of the RDC/TMD (available from the Consortium website, http://rdc-tmdinternational.org/translations/Prog050217.pdf) were employed. The history questionnaire (Axis II) of the RDC/TMD was translated into Malay by 2 bilingual translators using the back-translation technique established by Beaton et al.[11] The first stage is the forward translation. Two independent translators (a university language lecturer and a secondary-school headmaster) were used for this purpose. As a result, 2 independent Malay translations were produced.

Following this, a consensus committee (first meeting) comprising the translators, coordinator, and recording observers checked, compared, and homogenized the results of the translation. Any discrepancies in word choice were noted and resolved between the 2 translators. The recording observer helped synthesize the separate translations into a single common translation. This first translated version was edited.

The synthesized translated version was then back-translated into English (the source language) by 2 other independent translators (a university undergraduate student and a secondary school teacher; both understood the Malay language but were native English speakers).

The back-translation was then compared to the original English version to check equivalence, accuracy, and quality at a committee meeting (second meeting) made up of health professionals and language professionals, including both forward and backward translators. This was to ensure that the translated version reflected the same item content as the original version. A consensus on any discrepancy was reached, and if necessary, forward and back-translation were undertaken again until equivalence or near-equivalence was obtained (third meeting).

Adhering to the procedures and techniques described by Brislin,[12] a shared set of rules was used for translating certain nonequivalent words and phrases, poorly written language, and grammatical forms of the source.

Evaluation of Translated Version

Congruency Between Versions. The translated version of the RDC/TMD, the Mal-RDC/TMD, was compared to the original instrument to ensure that the meaning was retained. Items that were problematic were modified accordingly. A total of 30 subjects who were bilingual were recruited for the purpose of this study. They included healthy individuals as well as individuals with TMD symptoms. A cross-sectional crossover design was used to test for recall bias.[13]

Fifteen subjects completed the questionnaire in English and then in Malay. The next 15 subjects answered the translated version first, followed by the English version. The questionnaires were evaluated for congruencies or consistencies in the replies. Intrasubject variability was minimized by issuing the second questionnaire immediately after the first. However, the order of the items was rearranged to reduce recall bias.

The percentage of congruent scores (agreement) of the individual items reflected the agreement between the versions. The agreement rating of each statement in the questionnaire was calculated. Percentage of agreement is a measure of how often individual examiners agreed on the rating, which was used to indicate agreement of each statement in the questionnaire.[14] The formula used for computation was

$$\text{Percentage of agreement} = \frac{\text{No. of items on which there was exact agreement}}{\text{No. of possible agreements}} \times 100\%$$

All expert panel members agreed that the percentage of agreement should be no less than 90%. If the percentage of agreement was below 90%, the authors were to evaluate the translation again and make the necessary amendments to make any problematic items more culturally relevant.

Evaluation of Internal Consistency and Validity. A total of 40 TMD cases and 40 normal pain-free controls were recruited for the purpose of this study. These subjects were different from the ones used in the semantic equivalence study. Here, the subjects were not necessarily bilingual. Forty patients with TMD pain symptoms constituted "cases." These cases were derived from the outpatient and TMD clinics at the Dental Faculty, University Malaya, Kuala Lumpur. The cases were selected based on inclusion and exclusion criteria and willingness to participate in the study. The inclusion criteria for the TMD pain cases were the presence of pain in the jaw, temporomandibular joint regions, and adjacent areas either at rest or during jaw activity and the ability to comprehend and answer the questionnaires. Exclusion criteria were the presence of organic pathology related to the TMJ region, illiteracy, major medical history or psychiatric disorders, and inability to give consent.

Another 40 pain-free subjects from the community were recruited as normal controls. These were randomly selected individuals from parts of the Klang Valley in Kuala Lumpur, where this study was based. The control group comprised pain-free individuals without evidence of any signs and symptoms of TMD nor of any major illnesses and disorders. These individuals were literate and gave their consent to participate in the study. The study protocol was approved by the Ethics Committee, Faculty of Dentistry, University Malaya, Kuala Lumpur.

After signing the consent form, all cases and pain-free controls completed the Mal-RDC/TMD. Completion of the questionnaire provided baseline data for calculation of internal consistency, test-retest reliability, and discriminant validity. Internal consistency was evaluated by the use of Cronbach's alpha. Test-retest reliability data were collected by recalling 40 cases after 1 week. For the purpose of retesting, with the subjects' consent, treatment was only given after completion of the retest phase. At the retest visit, the questionnaire was again completed by all cases. The data collected the second time were compared with the data collected at baseline. The RDC/TMD domains of interest (Graded Chronic Pain Scale [GCPS], Depression, and Nonspecific Physical Symptoms [NSPS]) were presented in ordinal form (ie, levels of severity). Furthermore, raw scores derived from a standard formula[1] were taken as continuous measures. Test-retest reliability of the scores and levels were assessed using intraclass correlation coefficient (ICC) and Spearman's rho correlation, respectively. The values of ICC and Spearman's rho vary from 1 (perfectly reliable) to 0 (totally unreliable).[15] Discriminant validity was calculated by comparing the means of cases (n = 40) with means of controls (n = 40) using independent samples *t* test.

Following the completion of the retest phase, the TMD cases were given conventional conservative TMD treatment and were followed up at the TMD clinic. These cases also constituted part of the sample pool for Phase 2 of the main study. In the event that the results of preliminary version testing revealed incomparable internal consistency and validity[6] and a revision of the translated version was needed, these cases were to be eliminated from the Phase 2 study because in Phase 2, a reli-

Table 1 Congruency of Items of the Malay-English and English-Malay Versions of the RDC/TMD

Item description	No. of samples (out of 15) contributing to incongruence (% congruency)
How good a job do you feel you are doing in taking care of your oral health?	1 (93%)
In the last month, how much have you been distressed by awakening in the early morning?	1 (93%)
In the last month, how much have you been distressed by sleep that is restless or disturbed?	1 (93%)
In the last month, how much have you been distressed by feeling that everything is an effort?	1 (93%)
In the last month, how much have you been distressed by feeling of being caught or trapped?	1 (93%)
In the last month, how much have you been distressed by thoughts of death or dying?	1 (93%)
In the last month, how much have you been distressed by feelings of guilt?	1 (93%)

Table 2 Items Scoring Below the 90% Congruency Limit

Item no. (item description)	No. of incongruent samples out of 15 (% congruency)	Variance points: 1 out of 5 (no. of samples)	Variance points: 2 out of 5 (no. of samples)	Readjusted scores
20e…feeling blue	2 (87%)	1	1	93%
20l…worrying too much about things	2 (87%)	2	0	100%
20u…soreness of your muscles	2 (87%)	2	0	100%
20v…feeling hopeless about the future	2 (87%)	1	1	93%

Table 3 Internal Consistency (Cronbach's Alpha) of the Mal-RDC/TMD Axis II Measures of GCPS, NSPS, and Depression

Mal-RDC/TMD Axis II Measure (Domain)	No. of items	Cronbach's alpha: Average*	Cronbach's alpha: Lowest
GCPS	6	0.769	0.737
NSPS			
Total scale	12	0.769	0.731
Pain items excluded	7	0.657	0.556
Depression	20	0.870	0.860

*n = 40.

able and valid Mal-RDC/TMD was required for data collection.

All the reports and forms related to the translation process were submitted to the committee that kept track of the translation process. The committee verified that the recommended stages had been followed. No further alterations of the contents of the documents were made at this stage.

Measures

The measures of the Mal-RDC/TMD were categorized into 3 main domains, namely depression, NSPS (suggestive of somatization symptomatology) scales, and psychosocial function, measured on the GCPS. Cronbach's alpha, Spearman's rho, and ICC for these domains were calculated and charted.

The domain for GCPS was derived from items 7 to 9 and 11 to 13 of the RDC/TMD Axis II questionnaire. The domain for NSPS (inclusive of both pain and nonpain items) was derived from items 20a, c, d, j, o, p, r, s, t, u, w, and x. When pain items were excluded, the remaining domain consisted of items 20c, r, s, t, u, w, and x. Finally, the domain for Depression was derived from items 20 b,e, f, g, h, i, k, l, m, n, q, v, y, z, aa, bb, cc, dd, ee, and ff.

Results

Congruency

A total of 30 subjects participated in this study. Congruency results of the 15 subjects who completed the questionnaire in Malay followed by English were compared to those of another 15 subjects who did the reverse. Almost all the items scored 100% congruency, except for 7 items which scored only 93% (Table 1). Four items consistently scored below the 90% congruency limit (87%; Table 2).

The items which were incongruent were in the domain of psychological distress. These items exhibited either 1- or 2-point variances on the 5-point Likert scale. When variance of only 1 point was considered acceptable intrarater variability, the percent congruence was readjusted accordingly. Only items 20e ("feeling blue") and 20v

Table 4 Test-Retest Reliability (Spearman's rho and ICC) of Mal-RDC/TMD Axis II Measures of GCPS, NSPS, and Depression

RDC/TMD Axis II Measure	Spearman's rho	ICC		
		Single measure	Average measure	Lowest value
GCPS	0.930	0.932	0.965	0.922
NSPS (total)	0.753	0.891	0.942	0.882
NSPS (no pain items)	0.725	0.899	0.946	0.916
Depression	0.742	0.909	0.952	0.839

Table 5 Discrimination Validity of the Mal-RDC/TMD Axis II Measures of GCPS, NSPS, and Depression for Cases and Controls

RDC/TMD Axis II Measures	Mean		SD		SEM		
	Cases	Controls	Cases	Controls	Cases	Controls	*P*
GCPS	14.18	0.00	5.39	0.00	0.85	0.00	< .001
NSPS (total)	6.83	2.58	5.47	2.16	0.87	0.34	< .001
NSPS (no pain items)	3.48	1.20	3.38	1.48	0.53	0.23	< .001
Depression	10.55	3.30	7.80	3.50	1.23	0.55	< .001

[Difference between case and controls was $P < .001$ in all instances.

("feeling hopeless about the future") did not achieve a 100% congruence (Table 2).

Internal Consistency of Translation

A total of 40 TMD patients with symptoms of pain were used for testing the internal consistency of the Mal-RDC/TMD. The tests were grouped according to the different domains. Table 3 summarizes the internal consistency (Cronbach's alpha) of the Mal-RDC/TMD Axis II measures of GCPS, NSPS, and Depression. In general, a good level of internal consistency was demonstrated.

Test-Retest Reliability of Translation

The 40 subjects (TMD patients with pain symptoms) who were used for testing internal consistency were recalled a week later to assess for test-retest reliability. Spearman rho and ICC of the Mal-RDC/TMD Axis II domains are shown in Table 4. Results show that the test-retest reliability was high, as evidenced by the good to excellent Spearman's rho as well as the excellent ICC values. The lowest value was for NSPS (pain items excluded).

Validity of Translation

A total of 40 cases with pain symptoms were compared to 40 normal pain-free controls to test the discriminant validity of the items. The discriminant validity for the various domains is shown in Table 5. Most items (individual items; raw data) did not show significant differences between cases and controls, except for pain scores and the Depression and NSPS scales. Measures for GCPS, NSPS, and Depression were based on scores derived from a standard formula[1] and taken as continuous measures for calculations of mean, SD, and SEM. For a particular measure (eg, GCPS), the continuous scores of all the cases were compared to those of the controls and presented as mean values. Results show that the Mal-RDC/TMD was able to discriminate between normal subjects and cases in the relevant domains evaluated and that these differences were statistically significant (Table 5).

Discussion

Cross-Cultural Adaptation

Cross-cultural adaptation is a term used to encompass a process that looks at both language (translation) and cultural adaptation issues in the process of preparing a questionnaire for use in another setting.[11] It constitutes a prerequisite for the investigation of cross-cultural differences,[11] including the area of pain, which is influenced by the individual's unique environmental, psychologic, and socio-cultural makeup. In this study, the RDC was translated and cross-culturally adapted for use among the Malay-speaking population of multiracial Malaysia.

With regard to methodology, the translation and cross-cultural adaptation were carried out in accordance to the international guidelines advocated by Beaton et al.[11] The process consisted of 6 stages, each of which was documented by a written report. The translation and back-translation of the RDC proceeded without major difficulties. All the stages of the cross-cultural adaptation process were adhered to, beginning with initial translation and culminating in the submission of the final version to the translation committee of the RDC/TMD consortium. The translated version is available online at the RDC/TMD Consortium website.

Whether reliability, validity, and sensitivity to change should also be considered in the cross-cultural adaptation process has been a matter of controversy.[16] Because of subtle differences in the living habits in different cultures, the adaptation process could modify the reliability and validity of the instrument. Therefore it has been recommended that after the translation and adaptation process, the investigators ensure that the new version has demonstrated the measurement properties needed for the intended application.[11] With this in mind, the translation version of the RDC was further tested for internal consistency, reliability, and discriminative validity.

A culturally relevant system of care takes into consideration the cultural orientations of individuals by understanding and honoring attitudes, values, and behaviors unique to each person. These factors influence the ethnocultural qualities, needs, and expectations of the client system served,[17] as in the present study. Cross-cultural adaptation of the TMD, complete with the documentations of reliability and validity results, are available in German[18] and Dutch.[19] The data collected using a cross-culturally adapted RDC/TMD have provided a common measure for investigating TMD in Malaysia, allowing comparison with those of other international studies.

In the process of forward translation, no major difficulties were encountered in trying to find semantic equivalence, except for items 20l ("feeling blue"), of which there is no exact Malay equivalent. There is also no semantic core shared by the various terms, only a loose set of cross-cutting and overlapping semantic correspondences such as "muram," "murung," and "marah-marah." *Muram,* literally translated, means "dismal, gloomy, dull, or boring." *Murung* stands for "morose, gloomy, or distraught." *Marah-marah* means "moody with occasional angry feelings."[20] The Malay term *muram* was chosen over the others; it was considered the closest match and is frequently used to convey "feeling blue." This semantic difficulty was also reflected in the back-translation when this Malay term was back-translated into English as "feeling down."

At the pretesting stage, where 1 group of subjects completed the Malay version followed by the English version and another group did the reverse, the agreement rating of each statement in the questionnaire was calculated. All expert panel members agreed on the amendments in cases where the percentage agreement was beyond the critical value, which was set at the level of 90%. Other than the term "feeling blue," which was expected to evoke confusion among the respondents, 3 other terms or phrases also emerged as problematic: "worrying too much about things," "soreness of your muscles," and "feeling hopeless about the future," all of which produced percentage agreement scores of less than 90% (87%). This was due to 1- and 2-point incongruences (variance) on the 5-point Likert scale that was completed by the respondents. It was decided that a 1-point variance was acceptable. Following this decision, the percentage agreement scores were readjusted. All the items scored above the critical value of 90%. A similar critical value has also been used by others.[21]

The phrase "feeling hopeless about the future" also resulted in a 2-point variance. The phrase connotes a concept of hopelessness and helplessness which is not readily and openly admitted within the Malay culture, where hope and strength are renewed upon the grace of the Almighty. In Malaysia, the Malay identity is, to a large extent, shaped by Islam, which is the official religion of the nation and exerts a dominant influence in Southeast Asia.[22] Thus, it is the authors' belief that the response to the phrase "hopeless about the future" was inconsistent due to its implications, which are intertwined with religious beliefs, especially among the Muslim respondents. A more appropriate phrase for use among Muslim respondents to replace the current one requires further study.

Internal Consistency and Validity

The domains assessed for reliability and validity of the translated instrument were Depression, NSPS, and GCPS. These domains demonstrated high (> 0.74) internal consistencies comparable to those of the original RDC/TMD,[6,18,19] which also achieved good to excellent internal consistency. In the present study, however, the NSPS (pain items excluded) showed only slightly lower but acceptable internal consistency compared to the others. The results reflected the extent to which items measure the same characteristics even after the process of cross-cultural adaptation. The German version did not include

measures for somatization and depression because equivalent German instruments to assess these constructs ("Beschwerdenliste," "Allgemeine Depressionsskala") have well-established validity and reliability in the German cultural environment.[18]

Test-retest reliability estimates reflect the consistency of the individual examiner over time. In this study, the test-retest reliability, as represented by the ICC values, was acceptable, with most scales showing good reliability comparable to the results reported by John et al.[18] The average ICC for the GCPS domain was 0.97 (lowest ICC = 0.92), which was higher than the average value for the German version of the RDC/TMD (ICC = 0.92). For both Depression and NSPS, the ICCs were more than 0.94, and the lowest ICC was 0.839. The German scores were not available for comparison. For all the domains, Spearman's rho was more than 0.70 (lowest was 0.72 for NSPS with pain items excluded). These scores reflect good reliability comparable to those of other studies but could not be compared to scores for the original instrument, which were not available.[6]

The interpretation of the study results should also consider the different recall periods used in different studies. The present research was designed for a retest after 1 week[23,24] to minimize the discomfort and pain that the TMD patients had to endure before treatment began while also minimizing memory recall bias as a result of the first test. Despite these precautions, inconsistency, especially in the pain scores, was found in some TMD cases after the period of 1 week (in raw data collected), but the overall results were still good. This was not unusual, since pain intensities do vary over a period of time,[25] partly due to poor memory recall for pain.[26] Better consistency was found with the shortest recall period.[27] Retest results could also have been affected by the first test[14]; participants may have had difficulty in understanding the assessment process and had gathered a better understanding about the assessment, which could have affected the reassessment.

Prior validity studies have shown that the RDC Axis II should not be used for psychiatric diagnosis. Instead it assesses the extent to which a TMD patient may be cognitively, emotionally, or behaviorally impaired, which can contribute to the development or maintenance of the pain problem.[28] Because the purpose of the Axis II measures is to categorize patients into normal, moderate, or severe ranges of functioning based on symptoms and behaviors indicating psychologic disturbance, one aspect of validity of such Axis II measures, discriminant validity, was carried out in this study to distinguish TMD patients from asymptomatic pain-free controls. The discriminant validity of the translated version was assessed by its ability to differentiate symptomatic from asymptomatic subjects based on the presence or absence of TMD symptoms. TMD patients demonstrated significantly higher pain intensities and GCPS values compared to asymptomatic controls. The significant difference in the GCPS between TMD patients and asymptomatic controls can be largely attributed to the presence of pain in the former, where pain is a function of GCPS.[1] Furthermore, there were significantly higher scores for Depression and NSPS among TMD patients compared to asymptomatic controls, in concurrence with previous studies.[1,29] However, some of the relationships were not significant, showing that the RDC/TMD is not biased with respect to those characteristics such as demographic factors. Although the literature suggests a female preponderance for TMD, the sample size of the present study was too small for a statistically meaningful evaluation.

There are a few unaddressed issues associated with the present data. Firstly, a more complete psychometric evaluation of this translated instrument in relation to construct validity has not been presented. For an outcome measurement to be useful in clinical trials, it is essential that its items demonstrate change over time in response to a change in the subject's status; such change should be reflected in the sensitivity of pre- and post-treatment scores. There is also a need to ascertain further the generalizability of this translated instrument across the Malaysian population. The present study showed that the instrument could distinguish between symptomatic TMD patients and normal subjects in the domains evaluated, making it a reliable and valid indicator of depression, somatization, and psychosocial dysfunction. Construct validity, although desirable to ascertain, was not included in the study protocol due to time constraint. Construct validity analyses are already planned for implementation as part of a large-scale national effort to provide translation of the RDC/TMD in all 3 major languages spoken in Malaysia; these planned analyses will include all critical aspects of reliability and validity for each translation, with long treatment periods to observe change in the subject's status.

In summary, within the aforementioned limitations, this study has provided a valid and reliable cross-culturally adapted instrument for TMD researchers in Malaysia.

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